

GUIDELINES ON CLASSIFYING DEFICIENCIES IDENTIFIED DURING SEMIANNUAL REVIEWS

The fundamental basis of the relationship between an institution and the regulatory and accrediting organizations is the trust agreement between the parties. The following sentences are abstracted from the Institutional Administrator's Manual for Laboratory Animal Care and Use, NIH Publication 88-2959: "The Congress and PHS have mandated that institutions establish IACUCs to oversee programs of animal use with the objective that these committees form the foundation for effective self-regulation." "The PHS Policy requires the IACUC to evaluate the Animal Welfare Program, to identify the deficiencies, and to make recommendations for correction of deficiencies within a reasonable time. The IACUCs are charged by the Animal Welfare Act to inspect, at least semiannually, 'all animal study areas and animal facilities' and review, at a minimum, the condition of the animals and practices involving pain. Reports of the inspections and reviews are to be filed with the institution and are to include a description of all 'violations' and 'deficiencies' as well as minority views."

This guideline is intended to expand upon the specific language in paragraph IV. B. 3. of the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy), which states: "The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency."

SIGNIFICANT DEFICIENCY - A significant deficiency is any deviation(s) in policy, procedure or facility condition from the standards enunciated in the Guide for the Care and Use of Laboratory Animals (Guide), PHS Policy, or the Animal Welfare Regulations (AWRs), which is/are or may be a threat to the health and safety of the animals. Such a finding is one which the Institute or Center (IC) Animal Care and Use Committee (ACUC) collectively judges to be (or to have been) a major problem impacting negatively upon the health or safety of the animals and should be reported through the Scientific Director to the Deputy Director for Intramural Research (DDIR), NIH. If the finding was corrected on the spot or shortly thereafter, a report of that incident, as corrected, should be reported through the Office of Animal Care and Use (OACU) to the DDIR. In the event the correction of the underlying deficiency requires the execution of a planned modification or improvement over a period of time, then a reasonable and specific plan and schedule for correction must be established as quickly as possible and reported through the OACU to the DDIR. Those findings should again be addressed within the body of the next IC semiannual report. As a significant deficiency, by definition, is a threatening environment for the animals, it follows that the reasonable and specific plan and schedule for correction must indicate that management and/or policy changes will be put in place immediately to either; 1) remove the condition causing the significant deficiency until a permanent correction can be put in place; or 2) minimize the negative impact of the deficiency as much as possible and for as brief a period as possible.

The Office of Laboratory Animal Welfare (OLAW) has a high level of interest in significant deficiencies and would undoubtedly expect an institution to expedite appropriate resources

to correct the deficiency and bring the situation into compliance with applicable standards and regulations as quickly as possible. Normally, significant deficiencies would be viewed by OLAW as synonymous with "serious or continuing non-compliances with PHS Policy " or "serious deviations from the provisions of the Guide" and would require prompt reporting, in accordance with PHS Policy, IV, F.3.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) Council would probably view significant deficiencies as mandatory deficiencies, whether self-declared or noted during a site visit. A mandatory deficiency places an institution's accreditation status at risk and corrective actions for that deficiency must be accomplished within the time limit granted by Council.

MINOR DEFICIENCY - Any other deviation(s) in policy, procedure or facility condition from the standards enunciated in the Guide, PHS Policy, the AWRs, NIH Manual 3040-2, or IC policies and procedures, which are/were not justified exceptions to those standards. In comparison to the significant deficiencies noted above, minor deficiencies are variances which require correction but which are not serious breaches of policy or conditions endangering the health and safety of the animals.

The semiannual review process gives the ACUC an opportunity to formally and specifically deal with the entire scope of its IC's policies, procedures, and facility conditions in support of its Animal Care and Use (ACU) program. The degree of identification and reporting of minor deficiencies is a direct reflection of the thoroughness of the ACUC's oversight of its ACU program and facilities, and a very positive indication of their responsibility to the institution-at-large for performing effective self-regulation and concomitantly assuring continuing compliance with applicable regulations and standards.

In the event that an ACUC is dealing with a deficiency that remains uncorrected that deficiency should be highlighted in the recommendations made to the Institutional Official via the Scientific Director in the IC's semiannual report. In OACU's regular correspondence regarding the preparation of IC semiannual reports, a brief discussion will be included addressing the PHS Policy requirement that such recommendations be made to the Institutional Official and, if appropriate, to OLAW.

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